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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/914,658	02/15/2002	Gerd Hobom	Kreisler 1098-KGB	2342
27384	7590	04/07/2005	EXAMINER	
NORRIS, MCLAUGHLIN & MARCUS, PA			CHEN, STACY BROWN	
875 THIRD STREET			ART UNIT	PAPER NUMBER
18TH FLOOR			1648	
NEW YORK, NY 10022				

DATE MAILED: 04/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/914,658

Applicant(s)

HOBOM ET AL.

Examiner

Stacy B. Chen

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 January 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17, 23 and 25-27 is/are pending in the application.
- 4a) Of the above claim(s) 23 and 27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17, 25 and 26 is/are rejected.
- 7) ☒ Claim(s) 1-17, 25 and 26 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 August 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment filed January 18, 2005 is acknowledged and entered. Claims 1-17, 23 and 25-27 are pending. Claims 23 and 27 remain withdrawn from consideration being drawn to non-elected subject matter. Claims 1-17, 25 and 26 are under examination.
2. The objection to the specification for containing sequences that were not referred to by a "SEQ ID NO:" is withdrawn in view of Applicant's amendments to the specification. The objection to claims 9 and 10 is withdrawn in view of Applicant's amendment incorporating SEQ ID NOs into the claims.
3. The rejection of claims 18-22, 24 and 28-30 under 35 U.S.C. 112, second paragraph, is moot in view of Applicant's cancellation of claims 24 and 28-30, and withdrawn in view of Applicant's amendments.

Claim Objections

4. Claims 1-17, 25 and 26 are objected to because of the following informalities. The objections are solely based on incorrect grammar.
 - Claim 1 and all dependent claims recite the phrase, "A recombinant influenza virus for expressing of incorporated foreign gene(s)". This phrase is not grammatically correct.
 - Claim 4 is objected to because of a grammatical error in the phrase, "have been exchanged substituted by a foreign glycoprotein(s) or by fusion glycoproteins". There appears to be an extra word in this phrase.

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- Claim 5 also has a grammatical error in the phrase, “wherein said one or more promoter signals been modified”.
- Claim 6 and all dependent claims contain a grammatical error in the phrase, “wherein one or more RNA segment further comprises”. The phrase should be “wherein one or more RNA segment(s) further comprise”. There is also a grammar problem in the phrase, “and/or 13 nucleotide conserved influenza 5/ terminal sequence”. The phrase should be, “and/or a 13 nucleotide conserved influenza 5/ terminal sequence”.
- Claims 7 and 8, and all dependent claims are objected to because of a grammatical error in the phrase, “wherein the replacements in the 3’ terminal nucleotide sequence comprises the modifications”. There is a subject-verb agreement error.
- Claim 14 is objected to for a grammar error in the phrase, “claims 1”.
- Claim 16 and all dependent claims also contain a grammatical error in the phrase, “for vaccination purposes which comprising administering”.
- Claim 17 has grammar errors in parts (b) and (c). There should be an article before the subject, “form”. Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. Claims 1-17, 25 and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- Claim 1 and all dependent claims are unclear because of inconsistent terminology. In particular, the metes and bounds of the term “exogenous, recombinant gene” are unclear.

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The preamble of the claim mentions a foreign gene, however, Applicant uses different language to describe what appears to be the foreign gene as “exogenous, recombinant gene”. Also, the use of the term “endogenous viral RNA segments” and “eight viral RNA segments” is not linked. Consistent terminology is required to determine the metes and bounds of the claims.

- Claim 5 is unclear because of the use of the relative term, “increased transcription rates”, which lacks a comparative basis. The metes and bounds of “increased” rates are not defined.
- Claim 17 recites the limitation “the medicament” in claim 16. There is insufficient antecedent basis for this limitation in the claim.
- Claim 26 remains rejected for lacking complete method steps. Applicant has not recited method steps for somatic gene therapy beyond subjecting the organism to be treated with the recombinant influenza virus. In order for therapy to be accomplished, one must know what one is treating. The claim fails to point out and distinctly claim what is to be treated, or how the organism is “subjected”. In other words, the claim does not relate the therapy treatment with the foreign gene (to be expressed in the ambisense construct).

Conclusion

6. No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James C. Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.



Stacy B. Chen
March 29, 2005



JAMES HOUSEL 4/4/05
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600